

# Intellectual Property Issues for Health Care Providers

November 13, 2014



Michael Jones, Joseph Serritella and Peter Wakiyama



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# Intellectual Property Issues for Health Care Providers

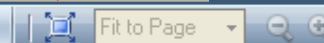
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Pepper Hamilton LLP  
Attorneys at Law



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Attorneys at Law

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# Intellectual Property Issues for Health Care Providers

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# Presenters



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Michael Jones is a partner in Pepper Hamilton's IP Transactions and Rights Management Practice Group and the Patent Litigation Practice Group. A registered patent attorney, Mr. Jones' practice focuses on all aspects of IP including strategic IP counseling and portfolio management, patent procurement (including domestic and foreign rights), patent opinions (including freedom to operate, non-infringement, invalidity, patentability), due diligence, licensing, and enforcing and defending patent rights. Mr. Jones counsels clients in a variety of industries and in a wide range of technologies.

# Presenters



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Joseph Serritella is a senior member in Pepper Hamilton's IP Litigation Practice Group and its original organizer. Mr. Serritella is a seasoned federal and state court litigator whose practice predominates in copyright, trademark, trade secret and like causes. In particular, Mr. Serritella is often involved in software copyright and trade secret disputes. Mr. Serritella also consults frequently with the department's transactions and rights management practitioners on pre-litigation aspects of IP-intensive deals, due diligence and ownership/availability assessments.

# Presenters



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Peter Wakiyama is co-chair of the firm's IP Transactions and Rights Management Practice Group. He focuses his practice on IP and technology law including IP and information technology transactions; general counseling, protection, enforcement and commercialization of trademarks, copyrights and other IP rights; Internet and e-commerce matters; and entertainment and the arts.

# Agenda/Topics

- Introduction
- Intellectual Property (IP) Basics
- IP Strategy
- IP Encountered by Health Care Providers
- Securing Ownership of IP Assets
- Managing/Registering IP Rights and Mitigating Infringement Risks
- IP Due Diligence In Business Transactions
- Q&A

# Introduction



- Why care about IP? Create valuable assets, improve competitive position in the marketplace, improve quality of goods/services, and minimize exposure/risk.
- Presenters:
  - Michael Jones
  - Joseph Serritella
  - Peter Wakiyama



- Patents
- Copyrights
- Trade Secrets
- Trademarks

# IP Basics – Patents

- A patent only lets the owner of the patent exclude others from making, using, offering for sale, importing or selling the claimed invention
  - A patent does not mean you can practice your invention
- Patents protect ideas, rather than creative expression *per se*
- Defined by federal law
  - U.S. Constitution Art. 1, Section 8
  - 35 U.S.C. § § 101, *et. seq.*
  - 37 C.F.R. § § 1.1, *et. seq.*
  - Manual of Patent Examination Procedure (MPEP)
- Limited term (20 years from filing)

# IP Basics – Patents (cont'd)

- Requirements
  - Must have some utility (35 U.S.C. §101)
  - Must be novel (35 U.S.C. §102)
  - Must be Non-Obvious (35 U.S.C. §103)
  - Must make disclosure (35 U.S.C. §112)
- How to obtain
  - Race to USPTO under America Invents Act (AIA) – First to File
  - Provisional or “full” utility applications
  - USPTO search/examination





- Copyrights cover a broad range of expressive content, but exclude any “idea, procedure, process, system, method of operation, concept, principle or discovery” embodied in the expression.
- Copyrights arise by operation of law without any formalities.
- The law imposes ownership unless altered by agreement: see e.g., “work for hire.”
- Exclusively federal law (17 U.S.C. §101, *et seq*)

# IP Basics – Copyrights (cont'd)



- Right to preclude
  - Copying
  - Compiling with other material
  - Distribution to the public
  - Creation of derivative works
  - Public performance, display or exhibition
  - By operation of preemption, assertion of “equivalent” state law-based rights
- Limited term
  - If created after 1/1/1978
    - By a human author, 70 yrs. past author’s death
    - By a fictitious author, 95 yrs. from publication or 120 yrs. from creation, whichever is earlier)



- Requirements
  - Original (*i.e.*, not copied from or derivative of pre-existing material)
  - Work of human authorship
  - Fixed in a tangible medium of expression
  - That can be perceived with or without the aid of a machine



- Trade Secrets can constitute any information not generally known that gives the beneficiary a competitive advantage
- State law-based
  - Existed in English common law and so finds its way into American state law – Reinstatement (First) or Torts §§ 757-59 (1939); Reinstatement (Third) of Unfair Competition §§ 39-45 (1995)
  - Uniform Trade Secrets Act (“UTSA”): Adopted by 46 states
  - Inevitable Disclosure Doctrine in subsequent employment: Adopted in some states and not others
  - Varying statutes of limitation
  - State law discrepancies can make choice of forum important for enforcement purposes
  - Federal, criminal overlay – 18 U.S.C. §1832, but creates no civil cause of action



- Right to preclude
  - Actionable against one who violates secrecy-in-fact
  - Action for breach of agreement to maintain secrecy
  - Agreement may include limited restraint on subsequent employment
- Duration is potentially unlimited, so long as:
  - Secret is not independently discovered by another (defense only for such a discoverer)
  - Secret is not published or otherwise becomes generally known through independent means (some states permit enforcement in this circumstance if defendant misappropriated from plaintiff, regardless of info being freely available elsewhere)



- Requirements
  - Protection is automatic so long as secret constitutes a competitive advantage and is maintained against disclosure
  - No registration possible, so no initial cost but imposition of Employment/Non-Disclosure Agreements, maintenance of true data security and enforcement can be burdensome/expensive

# IP Basics – Trademarks



- A word, name, symbol or device that indicates to the consumer both the source of goods or services, and the quality associated with the goods or services.
- Federal trademark law prevents one party from using a mark which is likely to confuse consumers as to the source or sponsorship of goods or services.
- After a mark is selected, trademark searches should be performed by counsel to determine if the mark is available (*i.e.*, no one is already using a confusingly similar mark).

# IP Basics – Trademarks (cont'd)



- Legal rights begin to accrue upon usage in connection with offering goods or services. Rights are limited to the geographic region in which the goods or services are offered.
- Registration with the USPTO is optional but confers significant statutory benefits, including the presumption that the registrant is entitled to use the mark exclusively nationwide for the stated goods or services.



# IP Basics – Trademarks (cont'd)



- “SM” is used to indicate a mark used in connection with services; “TM” is used to indicate a mark is used in connection with goods. ® is used to indicate that a mark is federally registered; it should never be used unless a mark is actually federally registered.
- A domain name may also serve as a trademark, depending on how it is used; accordingly, use of a domain name may infringe upon another party’s trademark. Before registering and using a domain name, the domain name should be cleared in a manner similar to trademark.



- IP Overview
  - What is IP?
    - A business tool
  - Forms of IP
    - Patents
    - Trademarks
    - Copyrights
    - Trade Secrets
    - Contracts / Agreements



- IP Strategy
  - What is Strategy?
    - A general method for achieving specific goals and objectives
    - It describes the essential resources and their amounts which are to be committed to achieving those goals and objectives
    - It describes how resources will be organized, and the policies that will apply for the management and use of those resources



- Premises of IP Strategy
  - A company's performance is highly correlated to its competitive position
  - One way to improve one's competitive position is to innovate
  - The output of innovation is IP
  - To effectively leverage IP, you must adopt an IP strategy



- Strategic Reasons For IP
  - Right to exclude
  - Hinder competitors
  - Preserve market share
  - Improve bargaining position / trading
  - Avoid litigation
  - Ability to effectively counter-sue
  - Corporate image / prestige
  - Entry to new markets
  - Profit center – royalties
  - Collateral for investments



- IP as Strategic Assets
  - Strategic assets
    - It not just protecting your technology
    - It's more – creating value for company
  - Innovation adds value – IP captures and protects that value
  - As such, IP should be managed as attentively as other company assets
  - Optimizing the value of IP
    - People
    - Process



- In Conclusion
  - Establish the Framework
  - IP should support business goals and objectives
  - Use IP to protect innovation and add value
  - Value may mean many things:
    - Keeping others from using the technology
    - Maintain freedom to operate
    - Disrupt others
    - Entry to new markets
    - Licensing the technology to others
    - Level the playing field
    - Gain recognition / prestige in the field

# IP Encountered by Health Care Providers – Patents



- Protecting Innovation
  - Filing patent applications
- Operating Business
  - Freedom to operate/clearance
- Avoiding Infringement
  - Non-infringement opinion
  - Invalidity opinion



# IP Encountered by Health Care Providers – Patents (cont'd)



US 20100106255A1

(19) **United States**

(12) **Patent Application Publication**  
DUBIN

(10) **Pub. No.:** US 2010/0106255 A1  
(43) **Pub. Date:** Apr. 29, 2010

(54) **SELF-EXPANDING FRONTAL SINUS STENT AND INSERTION TOOL**

(76) **Inventor:** Marc G. DUBIN, Pikesville, MD (US)

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(21) **Appl. No.:** 12/492,439

(22) **Filed:** Jun. 26, 2009

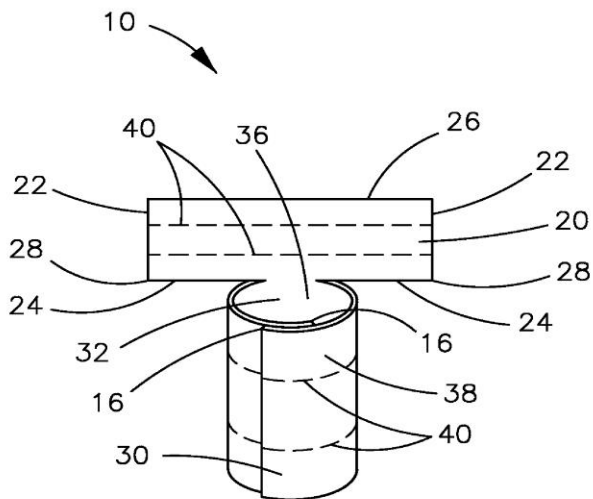
**Related U.S. Application Data**

(60) Provisional application No. 61/108,053, filed on Oct. 24, 2008.

**Publication Classification**

(51) **Int. Cl.**  
*A61F 2/04* (2006.01)  
*A61M 5/00* (2006.01)  
(52) **U.S. Cl.** ..... 623/23.7; 604/8  
(57) **ABSTRACT**

A self-expanding stent for use in maintaining patency of the frontal sinus drainage pathway and for the management of the frontal sinus postoperatively. The self-expanding frontal sinus stent helps maintain the pathway connecting the frontal sinus cavity open by filling this space and preventing restenosis of the frontal sinus drainage pathway following sinus surgery. The self-expanding stent may include a medical grade, flexible plastic material having with one or more recoil mechanisms having a memory to self expand. The self-expanding stent is compliant meaning that it may expand to the actual size of the space into which it is placed. The self-expanding stent may also be self-retaining. An insertion tool having the appropriate angulation and malleability may be used for ease of insertion of the self-expanding stent endoscopically into the frontal sinus. The use of a self-expanding frontal sinus stent and insertion tool for ease of insertion leads to less trauma for the patient and better surgical outcomes.



US 20100196865A1

(19) **United States**

(12) **Patent Application Publication**  
KAYS et al.

(10) **Pub. No.:** US 2010/0196865 A1  
(43) **Pub. Date:** Aug. 5, 2010

(54) **FLUID DELIVERY SYSTEM FOR PATIENT SIMULATION MANIKIN**

(75) **Inventors:** John A. KAYS, Palmyra, PA (US);  
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(21) **Appl. No.:** 12/366,454

(22) **Filed:** Feb. 5, 2009

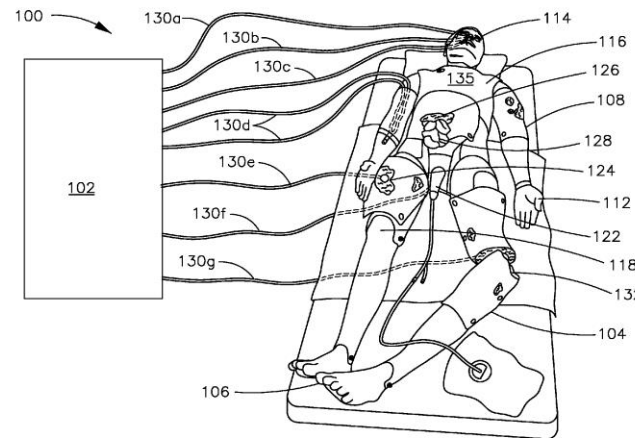
**Publication Classification**

(51) **Int. Cl.**  
*G09B 23/32* (2006.01)

(52) **U.S. Cl.** ..... 434/268

**ABSTRACT**

A fluid delivery system for remotely controlling the flow of simulated bodily fluids to a patient simulation manikin. The fluid delivery system may include multiple reservoirs for holding the simulated bodily fluids and multiple valves for controlling the flow of the simulated bodily fluids from the reservoirs to the manikin. The fluid delivery system may also include a fluid delivery component, such as a compressor or pump, for causing the simulated bodily fluids to flow from the reservoirs to the manikin. The reservoirs, the fluid delivery component, the valves, and the manikin may be interconnected to one another via tubing. The fluid delivery system may be controlled remotely from the manikin so that a trainee is not able to anticipate when the simulated bodily fluids will be delivered to and/or discharged from the manikin. The simulated bodily fluids may be delivered to the patient simulation manikin simultaneously and/or successively.



# IP Encountered by Health Care Providers – Copyrights



- All medical literature
  - Not surprisingly copyright covers journals, illustrations, photographs, drawings, diagrams, guidelines, protocols, product or procedure descriptions and more. The list is virtually endless. Consider also, for example, grant proposals, progress notes, video or audio recordings of interviews, rounds, surgeries, and the like, drafts of anything written, sketched or otherwise recorded, regardless whether or not a finished product.
- Computer programs
  - Everybody knows that software is present in data management systems, patient management systems, pharmacy management systems, communications systems, GUI's, and all manner of medical devices. This list too goes on. But did you know that almost every computer program is protected by copyright, unless it was created by the U.S. Government.
- Music, video and graphical recordings, downloads and streams
  - We are talking cable television, radio broadcasts and packaged music, among other sources, piped by the institution into patient rooms, the halls, elevators, operating theaters, or other public areas. All are protected by copyright. Also covered, and usually displayed illegally, are cartoon characters in the pediatric units.

# IP Encountered by Health Care Providers – Copyrights (cont'd)



- Advertising content and promotional materials, package inserts, instructions, any third party selling pieces, regardless of medium or method of dissemination, are covered by copyright.
- Photographs, paintings, sculpture
  - Artwork of all kinds that are exhibited in areas of institution that are available to the public, which includes any spaces where patients are permitted, such as exam rooms or lavatories. All such works are protected, not only against display and copying but also by “moral rights” of integrity and attribution.
- Not only are architectural plans and specifications covered by copyright but also some aspects of the resulting buildings themselves may be prohibited from being copied by others.

# IP Encountered by Health Care Providers – Trade Secrets

- Procedures, regimens, drug courses and other forms of medical technique that are known only to a limited circle and prevented from general disclosure, all can qualify as trade secrets.
- Computer programs. Aspects not revealed through operation of the program itself are almost universally considered to be trade secrets and can include prohibitions on reverse engineering the “black box.”
- Non-public financial and operating data, business development plans, fundraising strategies, any kind of commercially valuable information, not practiced by, or known to, others in the field can be preserved as trade secrets.

# IP Encountered by Health Care Providers – Trade Secrets (cont'd)



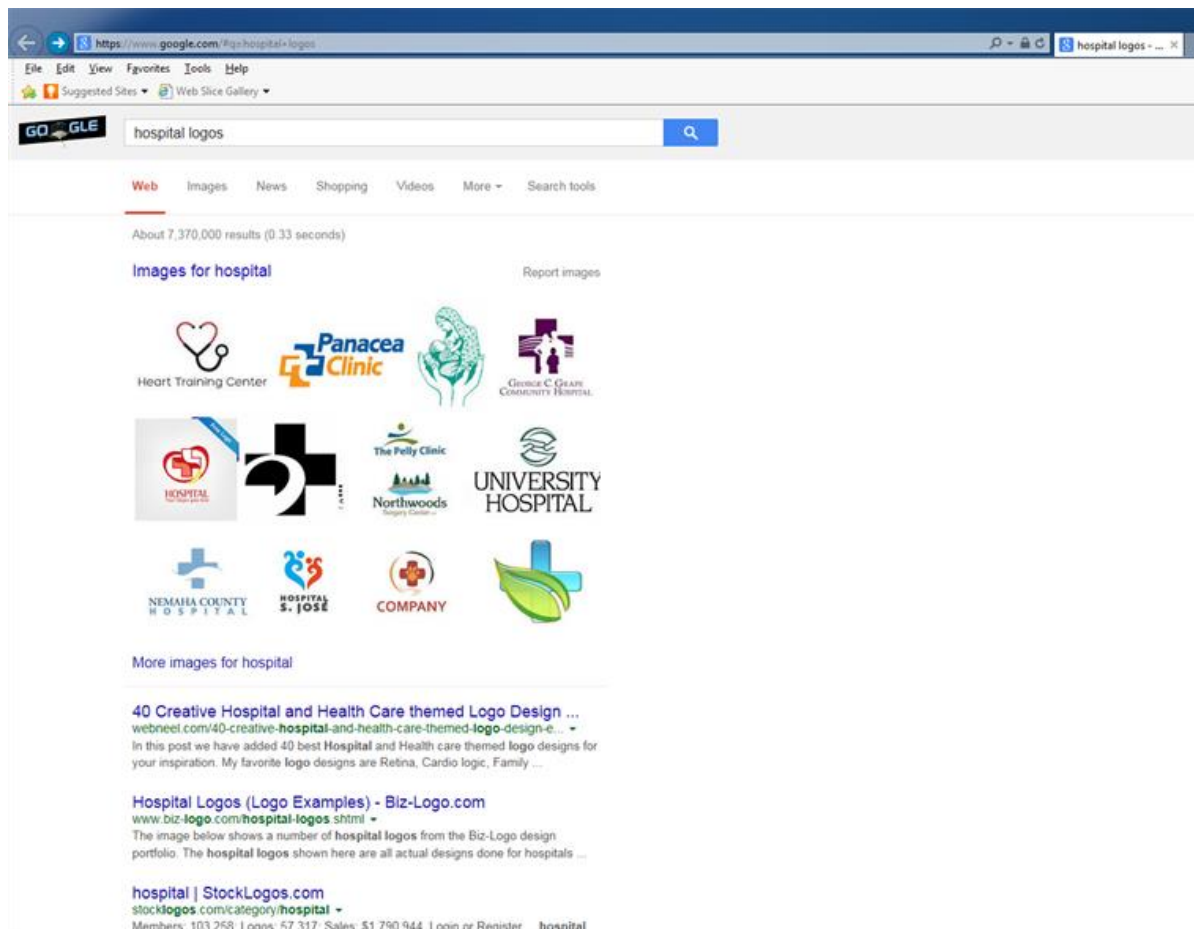
- At least, putative trade secrets can crop up anytime a contract has been signed, “clicked-through” or otherwise accepted that purports to impose confidentiality obligations on the institution or its employees. *See below.*
- New employee, supplier and even prospective supplier non-disclosure agreements (“NDA’s”) can entangle the institution. Beware of becoming exposed to claims made by pretextual opportunists.

# IP Encountered by Health Care Providers – Trademarks



- Name of provider, e.g., Mayo Clinic, CHOP, Cleveland Clinic.
- “taglines”, slogans and logos.
- Trade dress – for example, designs, colors, packaging.
- Website, mobile app and other distinctive online “look and feel”.
- Third party trademarks, co-marketing, co-branding, for example, sponsors and endorsements.

# IP Encountered by Health Care Providers – Trademarks (cont'd)



The screenshot shows a Google search for "hospital logos". The search results page displays a grid of various hospital logos, including:

- Heart Training Center
- Panacea Clinic
- George C. Gleason Community Hospital
- HOSPITAL (with a red cross)
- UNIVERSITY HOSPITAL
- NEMAHA COUNTY HOSPITAL
- HOSPITAL S. JOSE
- COMPANY
- The Pelly Clinic
- Northwoods (Hospitals of Colorado)

Below the grid, there are search results for:

- [40 Creative Hospital and Health Care themed Logo Design ...](#) from webneel.com
- [Hospital Logos \(Logo Examples\) - Biz-Logo.com](#) from biz-logo.com
- [hospital | StockLogos.com](#) from stocklogos.com

# Securing Ownership of IP Assets – Patents



- Whether an employer or inventor owns a patent depends on the agreement between the parties (as well as other factors).
- The general rule is that an inventor own the patent rights to the invention unless:
  - He/she signed an employment agreement assigning invention rights, or
  - He/she were specifically hired (even without a written agreement) for his/her inventing skills or to create the invention.
- Shop Right - even if an employer does not acquire ownership under one of these two methods, the employer may still acquire a limited right to use a patent without paying an inventor.
- Joint Inventorship – each inventor owns an undivided interest in the whole. As such each co-inventor can do as he/she see fit, without any accounting to other co-inventor(s).
- Each situation must be evaluated on its own set of facts.)



# Securing Ownership of IP Assets – Copyright and Trade Secrets



- Copyrights
  - A would-be copyright owner, or exclusive licensee, must obtain an appropriate signed, written transfer, except for the work product of full-time employees.
  - Effecting registration is not necessary to ownership but, as said, is a good practice to establish in an organization.
- Trade Secrets
  - Trade secrets can be procured by imposing time-of-hire confidentiality agreements on any employees likely to “discover” or develop hitherto unknown (or little known) products, methods, systems, techniques -- all of the forms of abstract knowledge and know-how that are *not* covered by patent or copyright.
  - Pursuing infringers, *i.e.*, suing or threatening those who disclose trade secrets without permission and those who receive trade secrets knowingly, most typically employers or fellow employees (responsibility still imparted to the employer), is also necessary to maintain protection. If such enforcement is effected in a timely fashion, it can sometimes “put the rabbit back in the hat.”

# Securing Ownership of IP Assets – Trademarks and Domain Names



- Trademark rights arise from use and vest in the party that adopts and uses a trademark; exception to this rule where user is a licensee.
- Trademark rights and any corresponding registrations may be assigned from one party to another, provided that all good will in the mark is assigned with the mark.
- It is advisable to have a written agreement that addresses ownership between the intended trademark owner and any party providing brand development services.
- Domain name registrations are owned by the party named in the registration; potential pitfall for the unwary if an employee or service provider names itself as the owner.

# Managing/Registering IP Rights and Mitigating Infringement Risks



## Patents

- Protect your IP
  - Patentability searching
  - Registration
- Be Aware of and Avoid IP Rights of Others
  - Searching and Opinions
    - Patentability
    - Clearance
    - Freedom to Operate
    - Non-infringement
    - Invalidity
- Address IP in Agreements
  - Types: Employment; license; supply; P.O.
  - Issues: Ownership; indemnification; representations and warranties

# Managing/Registering IP Rights and Mitigating Infringement Risks



## Copyrights

- One should post warnings and implement policies notifying personnel not to infringe copyrights. Even if ignored, this practice gives defense counsel an argument that infringements were not tolerated and so intent cannot be inferred against the employer. Also, while this may sound obvious, when a copyright infringement is detected, the institution should address it promptly and take the steps needed to remedy it (e.g., destroy infringing copies; discipline offenders).
- Be careful of copyright trolls (e.g., Getty Images), software trade associations (e.g., Business Software Alliance) and large software developers (e.g., AutoCad, SAP, GE Medical). The larger software owners, in particular, are given to initiating “voluntary” audits, seeking to detect, and often times over-detect, “rogue” copies of software on your systems.

# Managing/Registering IP Rights and Mitigating Infringement Risks



## Copyright Strategy

- Notwithstanding that copyrights spring into being upon creation, there is the constant necessity to marshal the ownership and/or the licensing of copyrighted works.
- The copyright law contains a statute of frauds, *i.e.*, copyright cannot be transferred without a writing signed by the owner of the rights. The so-called “work-for-hire” doctrine has many limitations, but the outstanding one is that it applies only to full-time employees; everyone else owns his, her or their (joint authorship) copyrights, by operation of law.
- Inbound licenses (*i.e.*, the right to exploit others’ copyrightable works) can be implied in law, implied in fact or granted orally. However, exceeding license restrictions results in infringement of copyright with various, even startling, remedies available to the copyright owner. You do not want to be an infringement defendant.

# Managing/Registering IP Rights and Mitigating Infringement Risks



## Benefits of Copyright Registration

- Applying to register a work forces the applicant to address the ownership maze on the front end. This is much more difficult to do after the fact, when bargaining leverage is lost, the people who knew what is what have departed, records have been lost and your counsel, or a lender, or an investor, or an acquirer, is putting on the pressure to register quickly.
- Registration is always necessary before U.S. nationals can enter the federal courts and sue on their rights. It is also necessary to recover attorney's fees and statutory damages; to enjoy these important, statutory benefits, registration has to have occurred prior to "commencement" of the infringement.
- Registration is often required by lenders, investors or acquirers, because it is a predicate to recording security interests against the copyrights or changes in ownership of the copyrights.
- Registration is cheaper, and frequently more accurate, when done in a consistent, orderly manner, immediately upon creation and prior to, or simultaneous with, publication. It is a best practice.

# Managing/Registering IP Rights and Mitigating Infringement Risks



## Trade Secrets

- The institution should employ confidentiality agreements, including NDA's, to protect its own secrets, even though protection is also available without an agreement under most states' laws.
- If you intend to own trade secrets, then keep them secret, in fact, and be prepared to police violators.
- The institution should make provisions to identify new secrets and, then, to keep them secret.
- Lastly, you should screen (e.g., interview) new employees to assure that they do not bring with them secrets from prior employers. If they have, you should take the steps needed to eradicate them from your systems, once found.



## Trademarks and Domain Names

- Conduct appropriate clearance searches before adopting and using a new trademark; multiple data bases and sources should be searched.
- Also conduct clearance searches for domain names where the domain name is likely to serve as an element of branding.
- When licensing the use of third party trademarks, obtain appropriate representations, warranties and indemnification against third party IP claims.





## Benefits of Federal Trademark Registration

- Public notice of your claim of ownership of the mark;
- A legal presumption of your ownership of the mark and your exclusive right to use the mark nationwide on or in connection with the goods/services listed in the registration;
- The ability to bring an action concerning the mark in federal court;
- The use of the U.S. registration as a basis to obtain registration in foreign countries;
- The right to use the federal registration symbol ®; and
- Listing in the United States Patent and Trademark Office's online databases.

# IP Due Diligence in Business Transactions



## What is it?

- The process of gathering information and assessing the merits, issues, and risks associated with the IP rights involved in business transactions

## When is it?

- Whenever a transaction involves the disposition of IP rights
  - Equity Investment
  - Loan Origination
  - M&A
  - IPO
  - IP Licenses

# IP Due Diligence in Business Transactions



- How much is enough?



# IP Due Diligence in Business Transactions

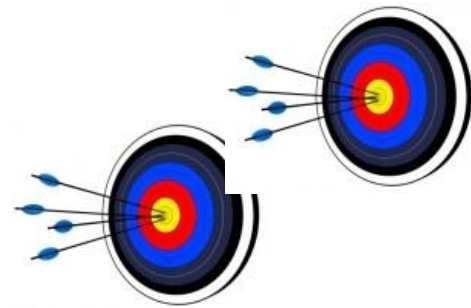
- Real world decision-making



# IP Due Diligence in Business Transactions



- Begin with the end in mind



# IP Due Diligence in Business Transactions



- Plan of attack
  - Have a plan
    - Due diligence team
      - Who is doing what and when
    - Scope of fact gathering
    - Issues for analysis
    - Timetable

# IP Due Diligence in Business Transactions



- Fact-Gathering
  - Identify all IP
    - Patents and pending applications
    - Trademark registrations and pending applications
    - Domain names
    - Copyrights
    - Trade secrets
    - Technical know-how



- Fact-Gathering (cont'd)
  - Confirm status of issued IP
    - Chain of title and ownership
      - Recordation of assignments
      - Rights of co-inventors
    - Licenses
      - Exclusive/non-exclusive
      - Scope, term, etc.
    - Patent maintenance/annuity fees
    - TM & domain name renewals



# IP Due Diligence in Business Transactions



- Risk Assessment
  - What are the key issues:
    - Ownership/Exclusivity
    - Coverage
    - Validity/Patentability
    - Freedom to Operate

# IP Due Diligence in Business Transactions



- Documenting the Deal
  - IP definitions
  - Reps and warranties
    - Knowledge qualifiers
    - Survival
  - Allocating risk
    - Indemnification
    - Escrows
    - Insurance

# IP Due Diligence in Business Transactions



- Copyrights
  - Do not accept work product that is based, in whole or in part, on a preexisting work.
  - Plagiarism is common in academia, which includes the segment of the medical profession which publishes. There are ways to root it out.
  - Copying software for a colleague to use, or for home use, is also a common copyright “no-no.”
  - Downloading unauthorized software from the Internet or other unlicensed sources, also can contaminate a system.
- Trade Secrets
  - Be aware of any circumstances wherein new employees, who might have been privy to former employer’s trade secrets, or current employees who may be misappropriating the secrets of others (“I came up with this idea, when in fact I lifted it from a restricted source.”). Such circumstances can contaminate your own information base and expose the business to liability in ways that can be extremely, both, expensive and embarrassing.

# IP Due Diligence in Business Transactions



- Trademark and Domain Name Due Diligence
  - Valid title? Search USPTO records for trademarks; verify status of registrations and applications; evaluate any recorded security interests and/or assignments
  - Scope of application or registration? Verify whether goods/services covered by the application or registration comport with goods/services actually being offered in connection with the trademark
  - Who actually owns the domain name? Search “who is” data base for domain names; identify current registrant; is registrant same owner as owner of any corresponding trademark registrations?
  - Was a proper clearance conducted? Investigate whether trademark clearance searches were conducted and whether counsel provided a clearance opinion
  - Sufficient geographic coverage? Evaluate whether the trademark has been established nationwide or if rights are more limited in scope, e.g., a specific state or region.

# Questions and Answers



**For more information,  
visit [www.pepperlaw.com](http://www.pepperlaw.com)**

